UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

VIRGIL BRADLEY,	
Plaintiff,	
Vs.	**Civil Case No:**
BIOMET, INC., BIOMET MANUFACTURING CORPORATION, BIOMET U.S. RECONSTRUCTION, LLC, and BIOMET ORTHOPEDICS, LLC.	**Master Docket No.: 3:12-md-02391 – RLM - CAN**
	HON. ROBERT L. MILLER.
	JURY TRIAL REQUESTED
Defendants	

COMPLAINT

COMES NOW VIRGIL BRADLEY, by and through his attorneys, and for cause alleges and states:

NATURE OF THE CASE

1. This is a product liability case filed on behalf of Plaintiff Virgil Bradley against Defendants Biomet, Inc., Biomet Manufacturing Corporation, Biomet U.S. Reconstruction, LLC and Biomet Orthopedics, LLC, who were responsible for the defective hip system implanted in Virgil Bradley, which caused him to undergo a revision surgery to remove the defective hip system.

VENUE

2. Venue is proper in the United States District Court for the Western District of

Arkansas, El Dorado Division, pursuant to 28 U.S.C. §1391(a)(2), as Defendants are corporations and corporations are deemed to reside in any judicial district where contacts would be sufficient to subject them to personal jurisdiction at the time the action is commenced, and a substantial part of the events or omissions giving rise to the claim occurred in this judicial district. The Defendants recommended, distributed, marketed, promoted, supplied and sold the Biomet M2a Magnum™ Hip System (M2a Magnum) to distributors, physicians, and hospitals within the state of Arkansas and specifically in the Western District of Arkansas at all times pertinent herein. Plaintiff is a resident within the jurisdiction of the Western District, El Dorado Division, of Arkansas. Plaintiff states that but for this Court's Order permitting direct filing into this Court (Master Docket No. 242), Plaintiff would have filed in the United States District Court for the Western District of Arkansas, El Dorado Division. Therefore, Plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings that this case be transferred to the United States District Court for the Western District of Arkansas, El Dorado Division.

JURISDICTION

3. This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1332 because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because complete diversity exists between the parties.

PARTIES

4. Plaintiff Virgil Bradley is an adult citizen of the United States of America and a resident of Emerson, Columbia County, Arkansas.

5. Upon information and belief, the Defendant, Biomet, Inc. is, and at all times relevant herein was a corporation organized and existing under the laws of the state of Indiana

with its principal place of business at 56 East Bell Drive, Warsaw, Indiana 46528. At all times relevant hereto, this defendant was conducting business in and/or having direct activities in the state of Arkansas.

6. Defendant Biomet, Inc. designed, manufactured, marketed, promoted and sold the M2a Magnum that is the subject of this Complaint.

7. Upon information and belief, Defendant Biomet Manufacturing Corporation is, and at all times relevant herein was, a corporation organized and existing under the laws of the state of Indiana with its principal place of business at 56 East Bell Drive, Warsaw, Indiana 46528. At all times relevant hereto, this defendant was conducting business in and/or having direct activities in the state of Arkansas.

8. Defendant Biomet Manufacturing Corporation designed, manufactured, marketed, promoted, and sold the M2a Magnum that is the subject of this Complaint.

9. Upon information and belief, Defendant Biomet U.S. Reconstruction, LLC is, and at all times relevant herein was, a wholly owned subsidiary of Defendant Biomet, Inc., an Indiana corporation with its principal place of business at 56 East Bell Drive, Warsaw, Indiana 46528, and at all times relevant hereto, doing business in and/or having direct activities in the State of Arkansas.

10. Defendant Biomet U.S. Reconstruction, LLC, designed manufactured, marketed, promoted, and sold the M2a Magnum that is the subject of this Complaint.

11. Defendant, Biomet Orthopedics, LLC is, and at all times relevant herein was, a wholly owned subsidiary of Biomet, Inc., an Indiana corporation with its principal place of business at 56 East Bell Drive, Warsaw, Indiana 46582, and at all times relevant hereto, doing business in and/or having direct activities in state of Arkansas.

12. Defendant Biomet Orthopedics, LLC, designed, manufactured, marketed, promoted, and sold the M2a Magnum that is the subject of this Complaint.

13. Defendants Biomet, Inc., Biomet Manufacturing Corporation, Biomet U.S. Reconstruction, LLC, and Biomet Orthopedics, LLC are collectively referred to herein as "Biomet" or "Defendants".

FACTS REGARDING PLAINTIFF

14. Plaintiff was a 58 year old male when he first presented to Kenneth Gati, M.D., orthopedic surgeon in El Dorado, Arkansas with complaints of having pain in his right hip. On examination he was found to have severe osteoarthritis of the right hip. Dr. Gati discussed these findings with Plaintiff and informed him that he was a candidate for a total right hip replacement. Plaintiff agreed and a right total hip replacement was performed on October 14, 2013 at the Medical Center of South Arkansas in El Dorado, Arkansas. A Biomet M2 Magnum System (metal on metal) was used as follows: Biomet M2A MAGNUM PF CUP, REF. US157862; Biomet E1 ACTIVE HEAD, REF. GTIN 008803044851 12; Biomet MODULAR HEAD COMPONENT, REF. 163638; and Biomet COLLARLESS POROUS STEM, REF 192512. On June 30, 2014, due to painful right hip, Plaintiff underwent a removal of the right hip loose acetabular component and replacement of the acetabular shell and liner with DePuy components, as well as removal and replacement of the head with a Biomet modular head by orthopedic surgeon Steven Atchison, MD at the Willis-Knighton Health System in Bossier City, Louisiana.

FACTUAL ALLEGATIONS

A. The M2a Magnum Is Defective And Was Not Adequately Tested

15. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the

acetabulum (a cup-like structure at the bottom of the pelvis). In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.

16. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) a plastic (polyethylene) liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.

17. While most hip replacements use a polyethylene plastic acetabular liner, Biomet's M2a Magnum has a critical difference: it is a monoblock system which does not have an acetabular liner. Instead, the M2a Magnum forces metal to rub against metal with the full weight and pressure of the human body. Because of Biomet's defective design for the M2a Magnum, hundreds of patients, including Plaintiff, have been forced to undergo revision surgeries to replace the failed hip implants.

18. The M2a Magnum suffers from a design or manufacturing defect that causes excessive amounts of cobalt and chromium to wear and corrode from the surface of the acetabular cup, from the femoral head, and from the taper adapter. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness, dislocation, and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die.

19. The design of the M2a Magnum was not sufficiently tested by Biomet.

20. On numerous occasions, Biomet met with orthopedic surgeons throughout the United States to promote the M2a Magnum. At some or all of these meetings, a representative or representatives of Biomet were present. During these meetings, Biomet assured the orthopedic surgeons that the M2a Magnum was safe, was the best product on the market, and had an excellent track record and a low and acceptable failure rate. Biomet continued to "defend" the M2a Magnum even after they became aware of numerous and serious complications with the M2a Magnum. Biomet did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons.

B. Biomet Sold the M2a Magnum to Plaintiff After It Knew It Was Defective, That It Had Injured Others, And That It Would Injure Plaintiff

21. It wasn't long after Biomet launched the M2a Magnum that reports of failures began flooding into Biomet.

22. Biomet would go on to receive hundreds of similar complaints reporting that the M2a Magnum had failed, and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed hip component. To date, thousands of adverse event reports associated with the M2a Magnum have been filed with the FDA.

23. By the time Biomet sold the M2a Magnum to Plaintiff, numerous reports had been filed with the FDA reporting an adverse event associated with the M2a Magnum. Consequently, Biomet was fully aware that the M2a Magnum was defective and that numerous patients had already been injured by that defect. Based on this information, Biomet should have recalled the M2a Magnum before it was sold to Plaintiff. At a minimum, Biomet should have stopped selling the defective implant when it became aware that it had catastrophically failed in several patients.

24. Despite its knowledge that the M2a Magnum had a defect and that it had failed

multiple times, causing numerous patients to undergo the agony of another surgery, Biomet continued to sell the defective M2a Magnum. In doing so, Biomet actively concealed the known defect from doctors and patients, including Plaintiff and Plaintiff's doctors, and misrepresented that the M2a Magnum was a safe and effective medical device.

25. As numerous failures of the M2a Magnum were reported to Biomet, it continued to actively promote, market and defend the defective product. For example, Biomet published marketing brochures touting the safety and durability of metal-on-metal implants and specifically, the M2a Magnum. These brochures were given to doctors around the world to encourage them to use the M2a Magnum.

26. Despite its knowledge that the M2a Magnum was defective, Biomet also made several false representations about specific design elements of the M2a Magnum that they claimed made it superior to other hip implants on the market. For example, Biomet said:

- "The M2a-Magnum Large Metal Articulation System offers optimal joint mechanic restoration and ultra low-wear rates in vivo."
- "Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

27. Biomet's reason to conceal the defect in its M2a Magnum is clear. Hip implant sales are critically important to Biomet, and the M2a Magnum is one of its most profitable products. During all times relevant to this Complaint, Biomet's management was trying to make Biomet look appealing to investors, and they ultimately were purchased by a private equity firm in 2007 for $10 billion.

28. Biomet was faced with a critical defect in one of its most profitable hip implant

systems. The last thing Biomet wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, Biomet decided that it would continue to promote, market, and sell the M2a Magnum despite the fact that it knew the product was defective.

C. Plaintiff Was Implanted With Defective M2a Magnum Products And As A Result Suffered Injuries

29. On October 14, 2013 Plaintiff Virgil Bradley underwent a right total hip arthroplasty procedure performed by Kenneth Gati, MD, at the Medical Center of South Arkansas in El Dorado, Arkansas. Biomet misrepresented to Mr. Bradley and his orthopedic surgeon that the M2a Magnum was safe and effective. In reliance on these misrepresentations, Mr. Bradley's orthopedic surgeon made the decision to use the M2a Magnum. If it were not for the misrepresentations made by Biomet, Mr. Bradley's orthopedic surgeon would not have used the M2a Magnum in Plaintiff's right hip replacement surgery.

30. Following his surgery to replace the right hip, Plaintiff began experiencing increasing pain around his implant that limited his mobility.

31. As a result of the defective design, manufacture and composition of the M2a Magnum, and its accompanying warnings and instructions (or lack thereof), Mr. Bradley's right hip implant failed, causing him severe pain, the need for revision surgery, and significant economic loss.

32. On June 30, 2014, Plaintiff underwent a complex, risky and painful revision surgery performed by Steven Atchison, MD, at the Willis-Knighton Medical Center in Bossier City, Louisiana to remove the defective M2a Magnum acetabular cup and femoral head. Revision surgeries are generally more complex than the original hip replacement surgery, often

because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the original hip replacement surgery and the revision surgery has a higher rate of complications.

33. Undergoing revision surgery has subjected Mr. Bradley to greater risks of future complications than he had before his revision surgery. For example, several studies have found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. In one study, conducted by Charlotte Phillips and her colleagues at Brigham and Women's Hospital in Boston, 14.4 percent of patients who underwent a revision surgery suffered from a dislocation compared with 3.9 percent of patients who underwent an original hip replacement surgery. (Phillips CG, et al. Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. *Am. J. Bone & Joint Surg*. 2003; 85:20-26.)

34. As a direct and proximate result of the failure of both his defective M2a Magnum systems and Biomet's wrongful conduct, Plaintiff suffered and continues to suffer the following personal and economic damages:

a) Undergoing additional surgical procedures that would not have been needed if the Biomet M2a Magnum devices had performed satisfactorily during their expected usual life;

b) Permanent harm by metallosis from the metal debris of the Biomet M2a Magnum;

c) Medical expenses (past and future);

d) Physical scarring (past and future);

e) Disfigurement (past and future);

f) Impaired physical mobility (past and future); and

g) Mental anguish and emotional distress (past and future).

As a result, Plaintiff has sustained, and will continue to sustain, damages in an amount to be proven at trial, but which will far exceed the $75,000.00 jurisdictional minimum of this court.

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT
(Against All Defendants)

35. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

36. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the M2a Magnum.

37. The M2a Magnum manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury and death.

38. As a direct and proximate result of Plaintiff's use of Defendants' M2a Magnum as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

39. Defendants' actions and omissions as alleged in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

40. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and

punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY -DESIGN DEFECT
(Against All Defendants)

41. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

42. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the M2a Magnum.

43. The M2a Magnum, manufactured and supplied by Defendants, was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

44. The foreseeable risks associated with the design or formulation of the M2a Magnum include, but are not limited to, the fact that the design or formulation of the M2a Magnum is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

45. As a direct and proximate result of Plaintiff's use of the M2a Magnum, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants and/or its failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

46. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

47. Plaintiff seeks actual and punitive damages from Defendants as alleged herein. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS
(Against All Defendants)

48. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

49. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the M2a Magnum.

50. The M2a Magnum, manufactured and supplied by Defendants, was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product and/or with applicable federal requirements.

51. Defendants made representations to consumers regarding the character or quality of M2a Magnum, including but not limited to statements that the M2a Magnum was a safe and durable hip replacement system. They further asserted that the Biomet metal-on-metal (MoM) M2a Magnum system offers optimal joint mechanic restoration, ultra low-wear rates in vivo, and that studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants.

52. Plaintiff and/or his physicians justifiably relied upon Defendants' misrepresentations regarding the M2a Magnum when they selected these Biomet orthopedic products to be used in surgery.

53. As a direct and proximate result of Plaintiffs use of the M2a Magnum, and Plaintiffs reliance on Defendants' representations regarding the character and quality of the M2a Magnum

and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

54. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

55. Plaintiff seeks actual and punitive damages from Defendants as alleged herein. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY - FAILURE TO WARN
(Against All Defendants)

56. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

57. The M2a Magnum was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the M2a Magnum, including but not limited to the risks of component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, the need for additional procedures to remove and replace the M2a Magnum, as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

58. At the time of Plaintiff's receipt and/or use of the M2a Magnum, the product was being used for the purposes and in a manner normally intended, namely for hip arthroplasty.

59. Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

60. Defendants, as manufacturers and/or distributors of the M2a Magnum, are held to the level of knowledge of an expert in the field.

61. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

62. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks, subjecting Plaintiff to risks that exceeded the benefits of the M2a Magnum, including but not limited to component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity, irritation and discomfort, the need for additional procedures to remove and replace the M2a Magnum, as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

63. Plaintiff, individually and through his physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

64. Defendants had a continuing duty to warn Plaintiff and his doctors of the dangers associated with the M2a Magnum.

65. Had Plaintiff and his doctors received adequate warnings regarding the risks of the M2a Magnum, they would not have used it.

66. As a direct and proximate result of Plaintiff's use of the M2a Magnum, and Plaintiff's reliance on Defendants' misrepresentations regarding the character and quality of the M2a Magnum and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

67. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

68. Plaintiff seeks actual and punitive damages from Defendants as alleged herein. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION
NEGLIGENCE
(Against All Defendants)

69. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

70. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the M2a Magnum into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events and/or a duty to comply with federal requirements.

71. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of the M2a Magnum into interstate commerce in that Defendants knew or should have known that the product caused significant bodily harm and was not safe for use by consumers, and/or through failure to comply with federal requirements.

72. Despite the fact that Defendants knew or should have known that the M2a Magnum posed a serious risk of bodily harm to consumers, Defendants continue to manufacture and market the M2a Magnum for use by consumers and/or continue to fail to comply with federal requirements.

73. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

74. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

75. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of the M2a Magnum when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

76. Plaintiff seeks actual and punitive damages from Defendants as alleged herein. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY
(Against All Defendants)

77. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

78. Defendants expressly warranted that the M2a Magnum was a safe and effective orthopedic device for those patients requiring a hip replacement.

79. The M2a Magnum, manufactured and sold by Defendants, did not conform to these express representations because it caused serious injury to Plaintiff when used as

recommended and directed.

80. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

81. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of the M2a Magnum when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

82. Plaintiff seeks actual and punitive damages from Defendants as alleged herein. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY
(Against All Defendants)

83. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

84. At the time Defendants designed, manufactured, marketed, sold, and distributed the M2a Magnum for use by the Plaintiff, Defendants knew of the use for which the M2a Magnum was intended and impliedly warranted the product to be of merchantable quality and safe for such use and that its design, manufacture, labeling, and marketing complied with all applicable federal requirements.

85. The Plaintiff and/or his physicians reasonably relied upon the skill and judgment of Defendants as to whether the M2a Magnum was of merchantable quality and safe for its intended

use and upon Defendants' implied warranty as to such matters, including that it was in compliance with all federal requirements.

86. Contrary to such implied warranty, Biomet's M2a Magnum was not of merchantable quality or safe for its intended use, because the product was defective as described above, and/or it failed to comply with federal requirements.

87. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

88. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of the M2a Magnum when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

89. Plaintiff seeks actual and punitive damages from Defendants as alleged herein. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACI'ION
NEGLIGENT MISREPRESENTATION
(Against All Defendants)

90. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

91. In the exercise of reasonable care, Defendants should have known that the M2a Magnum failed to comply with federal requirements for safe design and manufacture and/or was

in other ways out of specification, yet Defendants negligently misrepresented to the Plaintiff and/or his physicians that its device was safe and met all applicable design and manufacturing requirements.

92. The Plaintiff and/or his physicians reasonably relied to their detriment upon Defendants' misrepresentations and omissions in its labeling, advertisements, and promotions concerning the serious risks posed by the M2a Magnum. Plaintiff and/or his physicians reasonably relied upon Defendants' representations that the M2a Magnum was safe for use.

93. As a direct and proximate result of Defendants' negligent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its M2a Magnum, Plaintiff used Defendants' M2a Magnum and Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

94. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

95. Plaintiff seeks actual and punitive damages from Defendants as alleged herein. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

NINTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION
(Against All Defendants)

96. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

97. Defendants falsely and fraudulently represented to the medical and healthcare

community, Plaintiff, the FDA, and the public in general, that the M2a Magnum had been tested and was found to be safe and/or effective for hip arthroplasty treatment.

98. The representations made by the Defendants were, in fact, false.

99. When said representations were made by Defendants, they knew those representations to be false and they willfully, wantonly and recklessly disregarded whether the representations were true.

100. Defendants knowingly and intentionally made false representations of material fact to Plaintiff and his doctors, including but not limited to claims that the M2a Magnum was a safe and durable hip replacement system.

101. These representations were made by the Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase the M2a Magnum for hip arthroplasty treatment, all of which evinced a reckless and willful indifference to the health, safety and welfare of the Plaintiff and the general public.

102. At the time the aforesaid representations were made by Defendants, and at the time Plaintiff was treated with the M2a Magnum, Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

103. In reliance upon said misrepresentations, Plaintiff was induced to, and did use the subject product, thereby sustaining severe and permanent personal injuries including but not limited to significant pain, irritation and discomfort, as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

104. Defendants knew and were aware or should have been aware that the M2a Magnum had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

105. Defendants knew or should have known that the M2a Magnum had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or downplayed warnings.

106. Defendants brought the M2a Magnum to market, and acted fraudulently, wantonly and maliciously to the detriment of Plaintiff.

107. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its M2a Magnum, Plaintiff used Defendants' M2a Magnum and suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm and damages.

108. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

109. Plaintiff seeks actual and punitive damages from Defendants as alleged herein. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all other such relief as the Court deems proper.

TENTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT
(Against All Defendants)

110. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

111. At all times during the course of dealing between the Defendants and Plaintiff,

Plaintiff's healthcare providers, and/or the FDA, the Defendants misrepresented the safety of the subject product for its intended use.

112. Defendants knew or were reckless in not knowing that its representations were false.

113. In representations to Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants fraudulently concealed and intentionally omitted material information, including but not limited to, the fact that:

- the subject product was not as safe as other similar devices indicated for hip arthroplasty;
- that the subject product was defective, and that it caused dangerous side effects, including but not limited to the risks of developing component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, the need for additional procedures to remove and replace the M2a Magnum, as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices;
- that the subject product was manufactured negligently, defectively and improperly; and
- that the subject product was designed negligently, defectively and improperly.

114. Defendants were under a duty to disclose to Plaintiff, Plaintiff's healthcare providers, and/or the FDA the defective nature of the subject product, including but not limited to the risk of developing elevated metal ion levels and/or device failure resulting in the need for revision surgery associated with the use of the M2a Magnum.

115. Defendants had sole access to material facts concerning the defective nature of the M2a Magnum and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the M2a Magnum, including Plaintiff.

116. Defendants' concealment and omissions of material facts concerning the safety of the M2a Magnum was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and Plaintiff's physicians, hospitals and healthcare providers into reliance on the use of the M2a Magnum, and to cause them to purchase, prescribe, dispense and/or use the product.

117. Defendants knew that Plaintiff, Plaintiff's healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions.

118. Plaintiff, as well as Plaintiff's doctors, healthcare providers, and/or hospitals, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by the Defendants.

119. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its M2a Magnum, Plaintiff used Defendants' M2a Magnum and the Plaintiff suffered serious physical injury, harm, emotional distress, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

120. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

121. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all other relief as the Court deems proper.

ELEVENTH CAUSE OF ACTION
VIOLATION OF THE ARKANSAS DECEPTIVE TRADE PRACTICES ACT (A.C.A. § 4-88-101 et seq)
(Against All Defendants)

122. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

123. On October 14, 2013, Plaintiff was implanted with the M2a Magnum in his right hip, as manufactured, marketed and supplied by Defendants.

124. Plaintiff, Virgil Bradley, is a "consumer" as defined in the Arkansas Deceptive Trade Practices Act A.C.A. § 4-88-101 et seq.

125. Defendants are "suppliers" as defined in the Arkansas Deceptive Trade Practices Act.

126. The transaction involved in this case was a "consumer transaction" as defined in the Arkansas Trade Practices Act.

127. The conduct of Defendants in connection with the consumer transaction constituted unfair, deceptive and/or unconscionable acts or practices, in violation of the Arkansas Deceptive Trade Practices Act, including the following:

- representing that the M2a Magnum was safe, fit and effective for its intended use, knowing that these representations were false, and concealing that the M2a Magnum had a serious propensity to and did cause physical harm and injuries to users;
- engaging in advertising programs designed to create the image, impression, and belief by consumers like Plaintiff that the M2a Magnum was safe, even though Defendants knew these representation to be false; and

- issuing promotional literature deceiving potential users of the M2a Magnum by relaying positive information while downplaying the known adverse and serious health effects and concealing relevant information regarding the safety and efficacy of the product.

128. Defendants knew or should have known that the implantation of the M2aMagnum resulted in loosening and metal poisoning, among other injuries, requiring additional surgery to remove and/or repair the implant, and should have taken affirmative steps to warn consumers, such as Plaintiff of the potential harm of the product.

129. As a direct and proximate result of the Defendants' conduct, including but not limited to deceptive and unconscionable acts and practices, Plaintiff suffered and will continue to suffer great pain and anxiety and irreparable and catastrophic personal injury and damages.

130. Plaintiff further alleges that Defendants knowingly committed acts and practices in violation of the Arkansas Deceptive Trade Practices Act and is accordingly responsible for attorneys' fees.

131. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

TWELFTH CAUSE OF ACTION
PUNITIVE DAMAGES
(Against All Defendants)

132. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

133. At all relevant times, Defendants knew or should have known that their M2a Magnum was inherently more dangerous with respect to the risk of significant pain, irritation,

discomfort and need for additional surgeries than the alternative hip arthroplasty systems on the market.

134. At all relevant times, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the M2a Magnum.

135. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including Plaintiff, concerning the safety and efficacy of the M2a Magnum.

136. At all relevant times, Defendants knew and recklessly disregarded the fact that the M2a Magnum was subject to an increased risk of causing significant pain, irritation, discomfort and need for additional surgeries in persons implanted with the device with far greater frequency than safer alternative hip arthroplasty systems.

137. Notwithstanding the foregoing, Defendants continued to aggressively market the M2a Magnum without disclosing the aforesaid side effects, when there were safer alternative systems available.

138. Defendants knew of the M2a Magnum's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious disregard of the foreseeable harm.

139. Defendants' intentional and/or reckless, fraudulent and malicious failure to disclose information deprived Plaintiff and her surgeon of necessary information to enable them to weigh the true risks of using the M2a Magnum against its benefits.

140. As a direct and proximate result of Defendants' conscious and deliberate disregard for the rights and safety of consumers such as Plaintiff, Plaintiff herein suffered severe

and permanent physical injuries as set forth above.

141. The aforesaid conduct of Defendants was willful, wanton, and reckless, evidencing such an entire want of care as to raise the presumption of a conscious indifference to the consequences, and the conduct was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including Plaintiff, thereby entitling Plaintiff to punitive damages in an amount appropriate to punish the Defendants and to deter such conduct in these and other potential defendants from similar conduct in the future.

142. The Plaintiff seeks actual and punitive damages from Defendants as alleged herein. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all other such relief as the Court deems proper.

THIRTEENTH CAUSE OF ACTION
MEDICAL MONITORING
(Against All Defendants)

143. Plaintiff, as a result of the use of the Biomet M2A Magnum System, and the medical problems he has encountered as a result, is at increased risk of falls, further hip replacement surgery, metallosis, and other life threatening conditions and disabling injuries, and consequently, is entitled to medical monitoring at the expense of Defendants for the remainder of his life.

144. The medical monitoring that Plaintiff is entitled to includes, but is not limited to, physician evaluations and examinations, and care and treatment of the resultant medical conditions proximately caused by the M2a Magnum hip implant.

DAMAGES

145. As a result of his use of the Biomet M2A Magnum System, Plaintiff sustained the

following non-exclusive list of damages;

(a) Permanent Injuries;

(b) Past and future emotional and mental distress including, without limitation, justifiable fear of disease;

(c) Loss of enjoyment of life;

(d) Inconvenience;

(e) Past and future physical pain, suffering and disability;

(f) Increased risk of future hip replacements;

(g) Future medical monitoring;

(h) Past and future medical expenses;

(i) Loss of past earnings and future earning capacity; and,

(j) Other damages to be proven at the trial of this matter.

JURY TRIAL REQUEST

146. Plaintiff requests trial by twelve person jury on all issues.

WHEREFORE, premises considered, Plaintiff prays:

(a) That the Court enters judgment for Plaintiff against each Defendant, jointly and severally, for his pain and suffering, medical expenses, and economic losses, as proven at trial;

(b) That the Court enters judgment against each Defendant, jointly and severally, for all other general and compensatory damages allowable to Plaintiff;

(c) That the Court enters judgment against each Defendant, jointly and severally, for all other special damages allowable to Plaintiff;

(d) That the Court enters judgment against each Defendant, jointly and severally, for punitive damages under applicable law;

(e) That the Court enters judgment against each Defendant, jointly and severally, for all other relief sought by Plaintiff in this Complaint;

(f) That the costs of this action be taxed to Defendants; and

(g) That the Court grants Plaintiff such other and further relief to which she is entitled.

Respectfully submitted,

VIRGIL BRADLEY

/s/ Bobby Dean Davidson

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